

**REMARKS**

Support for the new claims can be found throughout the specification. For example: the prepro-urokinase (sc-uPA) is described on page 9, line 20 of the specification referring to Fig. 1(a) and also on page 9, lines 32-33 referring to SEQ ID NO:2. The HMW-uPA is described on page 9, line 33 to page 10, line 2 (reciting the amino acid sequence, SEQ ID NO:2). The amino-terminal fragment comprises acids 21-155 of the prepro-urokinase (sc-uPA) is described on page 10, line 2. Furthermore, it is described in the specification that the amino-terminal fragment of HMW-uPA, the HMW-uPA and the anti-CD87 antibody tested, which all bind to CD87, suppress HIV-1. Thus, it is shown in the specification that no B chain of the HMW-uPA, on which the catalytic domain of the enzyme resides, is needed. Also described is that the HMW-uPA has a cleavage between amino acids 178 and 179 (page 10, line 2). Thus, with reference to Fig. 1(c), it is substantially described in the specification that the Long A chain ends in amino acid 178 and that the B chain starts with amino acid 179, and that the Long A chain should have anti-HIV-1 activity since both a shorter chain consisting amino acids 21-155 and the longer HMW-uPA including this shorter chain process anti-HIV-1 activity. The fragment recited in claim 1 covers the fragment consisting of amino acids 21-155, the Long A chain, and the fragments falling between the two sequences.

Also with regard to claim 27, "injection, sterile", "aqueous medium", and "non-aqueous medium" appear on page 12, lines 24-33.

The fragment recited in claim 28 is described on page 10, line 2 of the specification.

With regard to claim 29, it is described in the specification that the amino-terminal fragment that was found active has the EGF-like domain, the Kringle domain and the urokinase receptor (CD87) binding domain of the HMW-uPA (page 9, lines 30-33). That no portion of the B chain of the HMW-uPA is needed as mentioned in item 2 above.

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With regard to claim 30, the word and phrase, "water" and "aqueous solution of one or more pharmaceutically acceptable inert solutes" appear on page 12, lines 26-27.

"Polyalcohols", "vegetable oils" and "organic esters" as "non-aqueous medium" appears on page 12, line 34 to page 13, line 2.

With regard to claim 31, the specification describes preparations for "transnasal or transpulmonary application" in the form of a "dry powder" (e.g., page 13, lines 16-19).

With regard to claim 34, the recited compounds forming the carrier are described on page 13, lines 21-28 and page 30, line 6, for example.

### **37. C.F.R. §1.74**

In accordance with Rule §1.74 as cited in the Office action, the detailed description of the invention contains a complete description of the drawings. For example, the figures are described in detail on Pages 9, 14, 15, and 23-27 of the specification.

No new matter has been introduced by the amendments to the Brief Description of the Drawings. For instance: Fig. 7 is described on Pages 22-23 of the specification; the Brief Description of the Drawings has been amended to include this language (e.g., Page 22, lines 27-30; Page 23, lines 5-11). Fig. 8 has been amended to include subject matter in the specification, e.g., on Page 23, lines 9-11. Fig. 9 has been amended similarly as Fig. 7.

### **Information Disclosure Statement**

A non-compliant Information Disclosure Statement (IDS) was indicated as being filed November 1, 2001. A copy of this document is not in the undersigned's files. However, an IDS was filed October 28, 2002. If this is not the IDS at issue, it is kindly requested that the examiner provide a copy of the IDS referred to in the Office action. It is believed that the October 2002 was fully compliant and filed with the listed publications. Nonetheless, it, along with the printed publications, is being resubmitted in the event that the publications were inadvertently misplaced.

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**35 U.S.C. §112, second paragraph**

Claims 1-5 and 8 were canceled, rendering the rejection moot.

**35 U.S.C. §112, first paragraph**

In accordance with the examiner's suggestion on Page 6 of the Office action, new claims have been added. This is not an acquiescence to the grounds of the rejection, nor a change to the scope of the original claims, but adds claims directed to subject matter disclosed in the originally filed application.

**35 U.S.C. §102(a)**

Enclosed is a verified translation of priority document Japanese Patent application No. 2001-042655, filed February 20, 2001, which establishes a priority date earlier than the publication date of Wada et al., BBRC, 284(2):346-351, June 2001 (Exhibit A). Thus, this reference is not prior art to the claims.

A verified translation of priority document Japanese Patent application No. 2001-184284, filed June 19, 2001 is also enclosed.

**35 U.S.C. §102(b)**

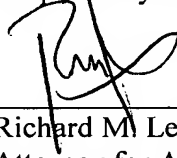
Stoppelli et al. do not disclose anti-HIV-1 pharmaceutical compositions, e.g., comprising sterile aqueous or non-aqueous medium or in the form of a dry powder. Since the reference fails to disclose each and every element of the claims, it cannot anticipate the claims.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

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The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Richard M. Lebovitz, Reg. No. 37,067  
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO  
& BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

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